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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,021	03/21/2005	Gary Eugene McVeigh	8830-296 (200898)	1950

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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	**PAPER NUMBER**
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,021	MCVEIGH, GARY EUGENE	
	Examiner	Art Unit	
	Katherine L. Fernandez	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed 10/19/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. There is no copy of the non-patent literature titled "Non-Invasive Ultrasonic Method for the Blood Flow and Pressure Measurements to Evaluate the Hemodynamic Properties of the Cerebro-Vascular System". It has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The disclosure is objected to because of the following informalities:

On pg. 5, lines 14-15, the sentence is unfinished.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3 and 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oruc et al. ("A comparative study on the effects of apraclonidine and timolol on the ophthalmic blood flow velocity waveforms", 1999) in view of Solomon et al. ("Determination of vascular impedance in the peripheral circulation by transcutaneous pulsed Doppler ultrasound", 1995).

Regarding claims 1-3 and 7-21, Oruc et al. disclose a study in which they used duplex scanning which combines B-mode and a Doppler ultrasound system as a noninvasive method to observe the hemodynamics of the ophthalmic artery (OA) and central retinal artery (CRA) as a response to apraclonidine 1% and timodol maleate 0.5% single dose administrations in a group of healthy young individuals (pg. 69, Introduction). They used Goldman applanation tonometry to record intra-ocular pressure measurements, and they further disclose that the mean intra-ocular pressure is measured (pg. 70, Materials and Methods:Subjects and Results). Their system further included using a doppler unit using a 5MHz Duplex pulsed wave Doppler transducer to serve as a blood velocity profile measurement means for measuring the linear blood flow velocity in the retrobulbar circulation (pg. 69-70: abstract and Methods:Doppler method). A B-scan image of the optic nerve was used to localize the optic disc (pg. 70, Methods: Doppler method). As disclosed by Oruc et al., the intraocular pressure measurements were followed by the Doppler investigations, and thus they were measured sequentially (pg. 70, Methods: Doppler method). They further disclose that impedance indices such as resisistivity index (RI) and pulsatility index(PI) were taken from Doppler measurements (pg. 70, Results and pg. 72, discussion).

However, they do not specifically disclose a means for calculating a vascular impedance modulus from the pressure pulse waveform and the linear blood flow velocity, as stated in instant claims 1 and 15. Further, they do not disclose the limitations of claims 12-14, 17, and 21 (i.e. calculating vascular impedance modulus by obtaining the fourier transform of the intra-ocular pressure pulse waveform and the linear blood flow velocity and dividing the transformed values of the pulsatile change in the intraocular pressure pulse by the transformed retrobulbar blood flow velocity, having a phase associated with the pressure and blood velocity, etc.).

Solomon et al. disclose a study to determine the vascular impedance spectra derived from measurements of blood flow velocity obtained by both noninvasive Doppler ultrasound and surgically placed electromagnetic flow probe in a canine common femoral artery (pg. 516, left column, first paragraph). Arterial pressure measurements and Doppler ultrasound flow velocity measurements were taken (pg. 516, Methods: Protocol 2). Further, they disclose that that Doppler ultrasound flow velocity waveforms were digitally recorded on a personal computer for subsequent analysis (pg. 516, Methods: Protocol 2). Solomon et al. disclose that the observed pressure and flow velocity data were translated into a Fourier series of sinusoidal waves (pg. 516, Methods: Data Acquisition and Analysis). Once converted into the frequency domain, the ratio of the amplitude of pressure harmonic frequencies to the corresponding flow velocity harmonic frequencies was calculated to give the impedance modulus as a function of frequency (pg. 517, Methods: Data Acquisition and Analysis). With regards to claims 13 and 14, Solomon et al. disclose that the pulsatile change in pressure and

the blood velocity has a phase associated with them (i.e. Solomon et al. disclose equations for calculating the phase for the pressure and flow velocity) (pg. 517, Methods: Data Acquisition and Analysis). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Oruc et al. to include a means for calculating a vascular impedance modulus (i.e. computer, conversion into frequency domain) from the pressure pulse waveform and the linear blood flow velocity, and to include the limitations listed in instant claims 12-14, 17 and 21. The motivation for doing so would have been that this would allow for an entirely noninvasive method for determining vascular impedance, as taught by Solomon et al. (pg. 520, Discussion, 2nd paragraph).

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oruc et al. in view of Solomon et al. as applied to claims 1-3 and 7-21 above, and further in view of Crutchfield et al. (US Patent No. 6,699,193).

As discussed above, Oruc et al. in view of Solomon et al. meet the limitations of claim 1. However, they do not specifically disclose that a solid state transducer is used to measure intra-ocular pressure, nor that that transducer operates in conjunction with a suitable telemetry system to process data. Crutchfield et al. disclose a system and method for assessing the vascular health of an individual (column 9, lines 14-16). They disclose that their system uses a data telemetry system to combine several unique technologies to assist physicians in control, management and delivery of improved, efficient, and timely medical care for patients (column 28, lines 42-45). Further, they disclose that parameters of blood flow may be determined using a Doppler velocimetry

technique, which uses an ultrasound beam from a transducer to produce a waveform of blood flow in the arteries using Doppler sonography (column 31, lines 33-43). Further, they disclose that data collected to determine the blood flow may include values such as mean blood pressure (column 31, lines 43-49). An automated decision support system can then provide a domain ontology for interpreting the values of these parameters derived from Doppler measurements (column 31, lines 33-40). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Oruc et al. in view of Solomon et al. to have a solid state transducer measure the intra-ocular pressure and operate in conjunction with a suitable telemetry system to process the data. The motivation for doing so would have been to provide the health care provider with the ability to conveniently and rapidly transmit vascular flow data parameters from a patient to a location where consistent, reproducible analysis is performed and to provide the parameters needed to assess vascular health (column 5, line 16 through column 6, line 57).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oruc et al. in view of Solomon et al. as applied to claims 1-3 and 7-21 above, and further in view of Spraul et al. ("Reproducibility of measurements with a new slit lamp-mounted ocular blood flow tonograph", 1998).

As discussed above, Oruc et al. in view of Solomon et al. meet the limitations of claim 1. However, they do not specifically disclose that an ocular pneumotonometer is used to measure intra-ocular pressure. Spraul et al. disclose a study to assess the reliability of measurements of intraocular pressure, pulse amplitude, and pulsatile ocular

blood flow (abstract). They used OBF Labs ocular blood flow tonograph with two different pneumatic probes in their study to measure the intra-ocular pressure. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Oruc et al. in view of Solomon et al. to measure intraocular pressure with an ocular pneumotonometer. The motivation for doing so would have been that ocular pneumotonometers have been shown to be reliable in measuring intraocular pressure, as taught by Spraul et al. (pg.278, 2nd column, 2nd and 3rd paragraphs).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER